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ATTACHMENT E

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 based on the format in the interim rule for 21 CFR § 807.92 as published in the Federal Register, April 28, 1992.

SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitter's Information:** Dated: June 22, 1995

Siemens Medical Systems
Oncology Care Systems Group
4040 Nelson Avenue
Concord, CA 94520

Contact Person: Kenneth R. Michael, Pharm.D.
Vice President Regulatory Affairs and Quality Assurance

2. **Common or Usual Name:** CT Option for Radiation Therapy Simulation System
Proprietary Name: **SIMPLI C.T.**
Classification Names: Radiation Therapy Simulation System - 21 CFR § 892.5840
Class II, Product Code: RA 90 KPQ

3. **Predicate Devices:**
- **SIMULIX-MC-CT-EXTENSION Oldelft Corporation of America**
  Treatment Planning Simulator, K912466
- **XIMATRON /CT, Varian Associates**
  Treatment Planning Simulator, K 853349, 82K0274

4. **Description of Device:**
The **SIMPLI C.T. Option** for the **SIMVIEW™ 3000** provides therapeutic quality CT images at simulation for use by the trained medical practitioner. It is similar in design to other such radiation therapy CT imaging simulation devices. The **SIMVIEW™ 3000** has microprocessor controlled solid state electronics, rotating gantry, patient support couch and accessories.

5. **Statement of intended use:**
The **SIMPLI C.T. Option** for the **SIMVIEW™ 3000** radiation therapy is used for the following:
1. To obtain CT images in the same position as the treatment.
2. To provide CT images to determine the contour of the patient.
3. To provide CT images to determine the size and location of internal structures.
4. To provide CT images to be used by the dosimetrist to determine the location of isocenter.
5. To provide tissue density information via Hounsfield numbers, which allows for more accurate calculations of the dose by accounting for variations in tissue densities. The intended use is the same as the predicate devices.

6. **Statement of technological characteristics:**
The **SIMPLI C.T.** for the **SIMVIEW™ 3000** radiation therapy simulation system has no significant change in design, materials, energy source or other technological characteristics compared to the predicate devices.

The intended use and the technological characteristics are the same as the predicate devices and therefore we believe it is substantially equivalent to them.

7. **Differences:**
The minor configuration differences between the **SIMPLI C.T.** for the **SIMVIEW™ 3000** and the predicate devices do not alter the intended use or affect the safety and effectiveness of the **SIMPLI C.T.** when used as labeled.

Special Controls:

Although there are no performance standards established by the FDA for these devices, the **SIMPLI C.T. Option** for the **SIMVIEW™ 3000** has been designed, and manufactured to meet the following standards:

IEC 601-1	Medical electrical equipment - General requirements for safety
IEC 601-1.1	Safety requirements for medical electrical systems
IEC 601-2-29	Particular requirements for the safety of radiotherapy simulators
IEC 1168	Radiotherapy simulators - Functional performance characteristics
IEC 878	Graphical symbols for electrical equipment in medical practice

Performance tests were conducted and the results indicated that the system consistently performed within the design parameters and equivalently to the predicate devices.